# EXHIBIT 3

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

**Center for Medicaid and State Operations**

**DATE:** OCT 2 2 2002

**TO:** Thomas A. Scully
Administrator

Ruben J. King-Shaw, Jr.
Deputy Administrator and Chief Operating Officer

**FROM:** Director
Center for Medicaid and State Operations

**SUBJECT:** Review of Medicaid Drug State Plan Amendments—**DECISION**

We are writing to seek your approval for criteria to be used for reviewing state plan amendments (SPAs) that seek to change the payment rates for drugs.

REDACTED

## BACKGROUND

*Estimated Acquisition Cost and Dispensing Fee*

There are two components of this payment rate. The first is Estimated Acquisition Costs (EACs), which means the estimated cost to the pharmacy of buying the drug. The second is the dispensing fee, which is the pharmacy's direct (e.g., packaging costs) and indirect (e.g., rent, electricity) cost of dispensing a drug. Each component is defined separately. The ingredient cost is defined in 42 CFR 447.301 as the state "...agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drugs most frequently purchased by providers." Dispensing fees must be "reasonable." The regulations require the state to describe the agency's payment methodology for prescription drugs "comprehensively" in the state plan.

In practice, we have told states that wish to modify their EAC levels that they must provide a factual basis to support a change in the EACs or dispensing fee. One method to support a change in EACs is to audit an appropriate number of pharmacies in order to determine current acquisition costs.[1] We have told the CMS regional offices (ROs) that in reviewing SPAs,

[1] States usually base the EAC on Average Wholesale Price (AWP) levels with a significant discount, e.g., AWP less 10 percent.

they may compare rates for contiguous states as well as for other states in the region. We have also said that they should consider drug cost studies. For the dispensing fee, we have said that states may establish a reasonable fee by: (1) conducting audits and surveys of operational costs; (2) compiling data regarding professional salaries and fees; and (3) analyzing compiled data regarding pharmacy overhead costs, profits, etc. For dispensing fees, we have told the ROs that they may, among other things, compare the proposed change to a related price index, e.g., the Consumer Price Index.

*Office of Inspector General (OIG) Reports and State Submitted Audits*

Recent OIG reports estimate the actual acquisition cost of brand name prescription drug products nationally to be, on average, the average wholesale price (AWP) less 21.8 percent. The OIG recently refined this number to differentiate it between those single source brand name drugs without generic competition and those innovator multiple source brand name drugs with generic competition. The OIG estimates that the single source brand name drugs cost, on average, AWP less 17.2 percent and the multiple source brand name drugs cost AWP less 24.4 percent. The OIG also studied generic drug discounts and found that the actual acquisition cost of generic prescription drug products nationally is, on average, AWP less 65.9 percent. Industry sources indicate that nationally, higher profit margins are obtained on generic prescription drug products.

State studies vary on the level of discount but generally are in the range of AWP less 20 percent to 35 percent.

**ANALYSIS**

REDACTED

REDACTED

**OPTIONS**

The following options are for approvals of SPAs; denials would be determined on a case-by-case basis.

*For ingredient costs (EACs) –*

1. Approve SPAs that decrease the ingredient costs as long as the costs are no lower than those of any other state that has maintained adequate pharmacy participation.

2. Approve SPAs that provide an aggregate decrease in the ingredient costs as long as the costs are no lower than the levels of costs found by the OIG (i.e., approximately 17 percent for single source, 24 percent for innovator multiple source, and 66 percent for generics), as long as the state can demonstrate adequate access.

3. Approve SPAs to increase payment for ingredient costs if the costs are less than the national median.

4. Approve rates set in state statute provided they meet one of the above three criteria.

*For dispensing fees –*

1. Approve SPAs with higher dispensing fees for generics.

2. Approve SPAs with increases in dispensing fees when the proposed fee is less than the national median.

3. Approve SPAs with decreases in dispensing fees when the proposed fee is no less than what is paid by any other state.

**RECOMMENDATION**

We recommend that we implement all of the above options. On SPAs that did not meet the above criteria, we would not automatically disapprove that SPA. We would look at the individual circumstances in the state as well as its supporting documentation and rational to decide whether to approve the SPA.

Dennis G. Smith

**DECISION**

Approve _____ _____
Signature Date

Disapprove _____ _____
Signature Date